K121919

Sec. 6: 510(k) Summary – EMM Surgical Drape with AAMI Liquid Barrier Level IV

Date Summary was Prepared	June 26, 2012
510(k) Submitter	David Nowicki, President Exact Medical Manufacturing Inc. 4917 William Street, Suite C Lancaster, NY 14086 dnowicki@exactmm.com (p)716-681-0866, (f) 716-681-4110 FEB 1 4 2013
Primary Contact for this 510(k) Submission	David Nowicki, President Exact Medical Manufacturing Inc. 4917 William Street, Suite C Lancaster, NY 14086 dnowicki@exactmm.com (p)716-681-0866, (f) 716-681-4110
Device Common Name	Surgical Drape
Trade Name	Surgical Drape with AAMI Liquid Barrier Level IV
Device Product Codes and Classification Name	KKX, 21CFR878.4370, Surgical Drape and Drape Accessories
Predicate Device	Kimberly Clark Corporation Surgical Drapes with AAMI Liquid Barrier Level 4 claim – K102666
Device Description	Exact Medical Manufacturing Surgical Drape AAMI Level 4 are sterile or non-sterile single use devices made of natural or synthetic materials intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination.. Exact Medical Manufacturing Surgical Drape with AAMI Liquid Barrier Level The base sheet fabric is a three layer composite comprised of polypropylene spunbond and a co-extruded PE film. Layers are thermally bonded together producing a single layer with various basis weights. The outer layers are non-woven fabric, the inner layer is AAMI PB:70 Level 4 capable PE film.
Intended Use	Exact Medical Manufacturing Surgical Drape AAMI Level 4 are sterile or non-sterile single use devices made of natural or synthetic materials intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination. The EMM Surgical Drapes AAMI Level 4 are also sold as bulk non-sterile, single use items, to repackager/relabeler establishments for further packaging and ethylene oxide sterilization according to ISO 11135-1:2007
Technological Characteristics	Exact Medical Manufacturing Surgical Drape with AAMI Liquid Barrier Level IV has the same design, material and performance characteristics and intended use as the predicate device.
Summary of Testing	Exact Medical Manufacturing Surgical Drape with AAMI Liquid Barrier Level IV is substantially equivalent and meets the same acceptance criteria as the predicate device/Drape in K102666 Non-clinical performance testing includes: Biocompatibility (cytotoxicity, irritation, sensitization) in compliance with the methods of ISO 10993, Barrier properties- AAMI PB:70 Level 4, tensile, tear strength, flammability, linting and sterility. All results of the testing met acceptance criteria.
Substantial Equivalence	The surgical Drapes described in this 510(k) submission are substantially equivalent in all specifications and performance compared to the predicate device indentified in K102666.

Exact Medical Manufacturing Surgical Drape with AAMI Liquid Barrier Level IV	Substantially Equivalent	Kimberly Clark Corporation Surgical Drapes with AAMI Liquid Barrier Level 4 claim 510(k)102666 PREDICATE DEVICE
Intended Use: Exact Medical Manufacturing Surgical Drape AAMI Level 4 are sterile or non-sterile single use devices made of natural or synthetic materials intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination. The EMM Surgical Drapes AAMI Level 4 are also sold as bulk non-sterile, single use items, to repackager/relabeler establishments for further packaging and ethylene oxide sterilization according to ISO 11135-1:2007.	Substantially Equivalent	**Intended Use**: The Kimberly-Clark* Surgical Drapes with AAMI Liquid Barrier Level 4 claim are devices made of natural or synthetic material intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination. These drapes meet the Level 4 requirements of the AAMI Liquid Barrier Classifications. The Kimberly-Clark* Surgical Drapes with AAMI Liquid Barrier Level 4 claim are also sold as bulk non-sterile, single use items, to repackager/relabeler establishments for further packaging and Ethylene Oxide (EtO) sterilization.
Classification & Code: Surgical Drapes and Drape Accessories, KKX, 21CFR878.4370, Class II	Substantially Equivalent	**Classification & Code**: Surgical Drapes and Drape Accessories, KKX, 21CFR878.4370, Class II
Single Use – Disposable	Substantially Equivalent	Single Use - Disposable
Barrier Performance: AAMI PB70: Level 4. ASTM F1670 – 08, Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood	Substantially Equivalent	**Barrier Performance**: AAMI PB70: Level 4
Materials & Construction: The base sheet fabric is a three layer composite comprised of polypropylene spunbond and a co-extruded PE film. Layers are thermally bonded together producing a single layer with various basis weights. The outer layers are non-woven fabric, the inner layer is AAMI PB:70 Level 4 capable PE film. Materials Weight per square meter Ref. P/N Description Weight/m^2 1 112005196-961 196cm/PMC04/Blue SMS 43 2 213408097 97cm/PMC02 BiLam Mtl 45 3 213408152 152cm/ BiLam Mtl 45 4 210401148-900 PSB3030 Pad 60 4 PE 25 **Color**: Blue **Dye**: Blue Colorant B373 (FB 1007)	Substantially Equivalent	**Materials & Construction**: The base sheet fabric is a three layer laminate comprised of polypropylene spunbond / polypropylene meltblown/polypropylene spunbond. Layers are thermally embossed together producing a single layer with various basis weights. Fabric is topically treated to enhance water repellency and to assure static dissipation. Unknown Color: Blue Dye: Unknown
Sterile (via EO Gas) ISO 11135-1:2007, Sterilization of health care products - Ethylene oxide - Part 1	Substantially Equivalent	Sterile via EO Gas
Sterile Packaging: Chevron peel pouch (coated paper (73gsm), PET12/PE40 film construction), individual CSR internal wrap	Substantially Equivalent	Flexible unit pouch
Non-Sterile bulk pack (alternate offering)	Substantially Equivalent	Non-sterile bulk pack
Biocompatibility: ISO 10993-5:2009 **Cytotoxicity**, ISO 10993-10:2002, **Skin Irritation**, ISO 10993-10:2002, **Sensitization**	Substantially Equivalent	tested for biocompatibility using cytotoxicity, primary skin irritation tests and sensitization testing.
Tear strength - ASTM 5587-08 (no rev.) Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure 19.4 lbs & 9.7 lbs	Substantially Equivalent	Tear strength - Unknown
Breaking strength - ASTM D5034-09 (no rev.) Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test) 24.4 lbs & 15.9 lbs	Substantially Equivalent	Breaking strength - unknown
Flammability - 16CFR1610:2007, Flammability of Clothing Textiles – Class 1	Substantially Equivalent	Class 1
Linting – ISO 9073-10:2003, Lint and other particles generated in the dry state	Substantially Equivalent	Linting - Unknown

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 14, 2013

Exact Medical Manufacturing, Incorporated
C/O Mr. Robert O. Dean
President
Compliance Systems International, Limited Liability Company
1083 Delaware Avenue
BUFFALO NY 14209

Re: K121919
Trade/Device Name: Exact Medical Manufacturing Surgical Drape with AAMI Level IV Liquid Barrier, Model #20-121, Blue
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: II
Product Code: KKX
Dated: January 7, 2013
Received: January 30, 2013

Dear Mr. Dean:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Runner, DDS, MBA
Mary S. Runner
2013.02.21
13:25:05 -05'00'

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

Indications for Use:

510(k) Number (if known): K121919

Device Name: Exact Medical Manufacturing Surgical Drape with AAMI Level IV Liquid Barrier, Model # 20-121, BLUE

Indications for Use: Exact Medical Manufacturing Surgical Drape AAMI Level 4 are sterile or non-sterile single use devices made of natural or synthetic materials intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination. The EMM Surgical Drapes AAMI Level 4 are also sold as bulk non-sterile, single use items, to repackager/relabeler establishments for further packaging and ethylene oxide sterilization according to ISO 11135-1:2007.

Prescription Use ____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Elizabeth F. Claverie
2013.02.15 18:16:47 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K121919